

EC Declaration of Conformity

HPC Healthline UK Ltd declares that the PPE described hereafter:

Handsafe Lightly Powdered Clear Vinyl Examination Glove (GN52)

- » is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard:

BS EN 420:2003 + A1:2009	Protective gloves – general requirements and test methods
BS EN 374-1:2003	Protective gloves against chemicals and micro-organisms - terminology and performance requirements
BS EN 374-2:2003	Protective gloves against chemicals and micro-organisms - determination of resistance to penetration
BS EN 374-3:2003	Protective gloves against chemicals and micro-organisms - determination of resistance to permeation

- » Is identical to the PPE which is the subject of EC certificate of conformity no. CE 585144 issued by British Standards Institute Group (BSI Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom.
- » Is subject to the procedure set out in Article 11 point A of Directive 89/686/EEC under the supervision of the approved body British Standards Institute Group (BSI Group), Kitemark Court, Davy Avenue, Knowhill, Milton Keynes, MK5 8PP, United Kingdom, under CE 585148 article 11A.

Done:

Signature:



Name: Scott Prichard

Place of Issue: Morden, UK

Position: Director

Date: 09 June 2015

File Ref: HPC-DOC-029 GN52 PPE

Revision: 2

Date of Issue: 09/06/2015

Page: Page 1 of 1

Declaration of Conformity

Manufacturer: HPC Healthline UK Limited, Colwood House,
158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

Product: GN52 Lightly Powdered Clear Vinyl Medical Examination Glove

Brand Name: Handsafe

Classification: Class I (According to Annex IX, Rule 5 of Council Directive 93/42/EEC, as amended by directive 2007/47/EC).

Conformity Assessment Route: ANNEX VII: Self declaration that the products of this declaration meet the provisions of Council Directive 93/42/EEC, as amended by directive 2007/47/EC.

Harmonised Standards: Medical gloves for single use:

- BS EN 455-1 Freedom from Holes
- BS EN 455-2 Physical Properties
- BS EN 455-3 Biological Evaluation
- BS EN 455-4 Shelf Life Determination

HPC Healthline UK Limited hereby declares that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for Medical devices, as amended by directive 2007/47/EC.

Signature:



Name: David Greenwood

Place of Issue: Morden, UK

Position: Director

Date: 15th June 2016

File Ref: HPC-DOC-078 GN52 MDD

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Page: Page 1 of 1

Food Contact - Declaration of conformity



For materials intended to come into contact with food

Manufacturer: HPC Healthline UK Ltd, Colwood House,
158 Garth Road, Morden, Surrey, SM4 4LZ

Product: GN52 Lightly Powdered Clear Vinyl Examination Gloves

Brand Name: Handsafe

HPC Healthline UK Ltd hereby declares that the above mentioned products are in compliance with the rules of:

- Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

and meet the demands of:

- Commission Regulation (EU) No 10/2011 of the Commission of 14 January 2011 on materials and articles made of plastic which are intended to come into contact with food.

and were examined under the OEM brand according to:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 and Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on plastic materials and articles intended to come into contact with food.
- EN1186-1:2002 for test method (materials and articles in contact with foodstuffs – plastics) – overall migration.
- EN13130-12004 for sample preparation for testing with ICP-OES analysis for migration of heavy metals.
- SHTC-CHEM-SOP-171-T SGS in-house method for vinyl chloride monomer.
- EN13130-12004 for sample preparation for testing with GC-MS for the specific migration of phthalates.

The Handsafe GN52 clear vinyl gloves are permitted for contact with the following specific food types:

» Aqueous foods » Alcoholic foods » Acidic foods » Dry foods

They are **not** permitted for use with: » Fatty foods

This declaration is supported by Test Reports:

» TAOHG1202339401 : SH7030423/CHEM : SP070400463-1 SGS, China

K. Gunning

QA and Regulatory Affairs Manager

25th November 2013

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Page: Page 1 of 1



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